UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

THE CITY OF HUNTINGTON, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, *et al.* Defendants	Civil Action No. 3:17-01362
CABELL COUNTY COMMISSION, Plaintiff, v. AMERISOURCEBERGEN DRUG CORPORATION, *et al.* Defendants	Consolidated Case: Civil Action No. 3:17-cv-01665

PLAINTIFFS' RESPONSE TO MEMORANDUM IN SUPPORT OF CARDINAL HEALTH'S MOTION FOR JUDGMENT RE: UNREASONABLE INTERFERENCE WITH A PUBLIC RIGHT

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

CASES

COURT RULES

Other Publications

PRELIMINARY STATEMENT

Plaintiffs' evidence overwhelmingly demonstrates that Cardinal behaved unreasonably in its distribution of dangerously addictive prescription opioids, thus providing the predicate culpable conduct for a finding of public nuisance. Given the dangerous and addictive nature of these drugs, it was necessary for Cardinal to control their distribution and to take steps to prevent diversion for illegitimate purposes. Cardinal created national policies that purported to provide tools to prevent diversion, through the identification of so-called "suspicious orders," those with indicia of diversion. But these tools were not, in fact, effective in preventing diversion and Cardinal did not, in any event, seriously implement them. Its failure to control the supply chain for the dangerous drugs it was distributing was unreasonable and created a public nuisance, when inevitably and predictably, the drugs were diverted. In particular, the evidence shows that Cardinal Health's distribution of prescription opioids was unreasonable because:

- Cardinal's program for detecting "suspicious orders" of prescription opioids was not designed to, and could not, detect a significant percentage of orders that were sufficiently unusual in volume, pattern, or frequency to be indicative of diversion;
- Cardinal failed to perform due diligence on opioid orders it knew were suspicious to determine if diversion was likely, shipped orders of prescription opioids it knew were suspicious without first ascertaining that those orders were not likely to be diverted, and continued shipping opioids to pharmacies that it knew showed indicia of diversion;
- Cardinal failed to properly implement the suspicious order monitoring (SOMs) program that it did have;
- Cardinal distributed just over 37 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell-Huntington, between June, 2002 and December of 2018, the equivalent of 370 doses for every man, woman, and child in the community, an amount that was, in and of itself, unreasonable and could not be explained by changes in the standard of care for treating pain;
- Cardinal knew that its anti-diversion programs were inadequate, and knew the devastating effects of the failure to maintain controls against diversion, but failed to make changes to address the inadequacies;

- Cardinal's failure to detect, investigate, and halt suspicious orders violated the federal Controlled Substances Act ("CSA"), which sets the standard of care for reasonable conduct in the distribution of dangerous narcotics.

This evidence is sufficient to establish Cardinal Health's culpable conduct, and under West Virginia law, liability for public nuisance.[1]

RULE 52(C) LEGAL STANDARD

Plaintiffs incorporate the Legal Standard as set forth in Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Judgment on Partial Findings on Causation (Dkt. 1469).

THE EVIDENCE

I. CARDINAL HEALTH'S NATIONAL POLICIES WERE NOT DESIGNED TO, AND COULD NOT, DETECT SIGNIFICANT QUANTITIES OF SUSPICIOUS ORDERS

The evidence introduced at trial shows that, throughout the time period at issue in this case, Cardinal lacked SOMs policies that were capable of detecting significant numbers of orders with indicia of diversion – that is, those that were suspicious because of their size, volume, or frequency. This was true of the policies that Cardinal maintained before 2008, and was also true of later policies that Cardinal implemented in 2008.

A. Cardinal Health's Pre-2008 Anti-Diversion Policies Were Inadequate to Detect Suspicious Orders

Prior to 2008, Cardinal Health's QRA department operated without sufficient resources or personnel.[2] Only 2-3 people manually reviewed ILRs from 2005-2008.[3] The head of the QRA

[1] This response addresses only the first argument raised by Cardinal's Motion. *See* Doc. 1446-1 at pp. 3-24. Plaintiffs have previously responded to Cardinal's arguments related to causation, *id.* at 24-40. See Doc. 1469 (Pltfs' Memo. of Law in Opposition to Defendants' Motions for Judgment on Partial Findings on Causation). Plaintiffs' response to Cardinal's arguments relating to abatement, Doc. 1446-1 at pp. 40-71 appear in Plaintiffs' Consolidated Response to Defendants' Motions for Judgment Re: Abatement, Doc. 1470.

[2] Lawrence, 10/1/2020 Depo at 200.

[3] Brantley, 10/1/2020 Depo at 150-151; 363.

department at that time, Steve Reardon, agreed three people was insufficient.[4] Michael Moné testified that when he took over the role of head of anti-diversion in 2007, the three people working in the department was insufficient.[5]

Until 2008, Cardinal's SOMs relied on Ingredient Limit Reports (ILRs) and distribution center employees' daily observation of individual orders to identify suspicious orders.[6] Both of these were facially insufficient and failed in practice to comply with the CSA's requirements.

Cardinal Health's distribution centers separately submitted ILRs to the Drug Enforcement Agency ("DEA") each month that identified Cardinal customers whose total monthly purchases of schedules II-V drugs exceeded a predetermined limit.[7] Each ILR was hundreds of pages long and identified orders that Cardinal had determine were suspicious.[8] None of the orders identified in ILRs were reported to the DEA before they were shipped to Cardinal's customers.[9]

These thresholds were based on the average monthly grams of each drug base code purchased by each class of customers (retail pharmacies, hospitals/managed care, and other).[10] For opioids sold to retail customers, Cardinal multiplied that average by a factor of four to arrive at the limit for that month.[11] Each Cardinal distribution center generated its own report, and the system was the same across the country.[12]

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[4] Reardon, 11/30/2018 Depo at 469-470.

[5] 5/20 Trial Tr. (Moné) at 52; P-09734.

[6] P-14290.

[7] P-14290; P-14288.

[8] Reardon, 11/30/2018 Depo at 426-427.

[9] Reardon, 11/30/2018 Depo at 427-427.

[10] The Chemical Handlers manual is designed to identify extraordinary orders of List I chemicals and is not applicable to controlled substances. 5/20 Trial Tr. (Moné) at 94-95.

[11] P-14288.

[12] 5/20 Trial Tr. (Moné) at 40-41.

During this period, while Mr. Reardon oversaw Cardinal's Anti-Diversion Department, he was not even aware of Cardinal's obligation under the CSA to maintain effective controls to prevent diversion. He was only aware of the regulation regarding suspicious orders. He also acknowledged that Cardinal's ILR system and subsequent investigation was not sufficient to maintain effective controls against diversion.[13]

Prior to 2008, Cardinal also relied on distribution center warehouse workers, called pickers and checkers, to manually flag orders that exceeded dosage limits set for specific drug formulations (morphine tablets versus liquids, for example) and to flag the excessive purchases. According to Cardinal's policy, the limits were set "by calculating average sales quantities for Knoxville's retail customers and Boston's hospital customers and multiplying by 3" for opioids.[14] Cardinal's system did not consider the frequency or pattern of orders that should have allowed it to make informed decisions to investigate and cancel certain shipments to its pharmacy customers that the governing regulations defined as suspicious.[15]

The limits were posted in charts in the cage or vault for pickers and checkers to compare with the orders they were preparing for shipment.[16] These employees had no background in compliance nor guidance on how to identify potentially suspicious orders.

There is no evidence that Cardinal ever identified a single excessive purchase report for any customer serviced by the Wheeling, West Virginia distribution center.[17]

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[13] Reardon, 11/30/18 Depo at 416-418; 469-470; 453.

[14] P-14290_00147.

[15] *See* 21 CFR 1301.74(b).

[16] P-14290; Reardon, 11/30/18 Depo. at 492-493; Brantley, 10/1/20 Depo at 533.

[17] P-23656 (Response to Request No. 3).

B. Cardinal Health's Anti-Diversion Policies from 2008 Forward Remained Inadequate to Detect Suspicious Orders

The electronic suspicious order monitoring system Cardinal implemented nationally in 2008 utilized a threshold based on average sales of controlled substances multiplied by a factor of 3. This meant that Cardinal used opioid epidemic level numbers to set thresholds for its customers.[18]

By the time it put thresholds in place, Cardinal knew that the opioid epidemic was already underway. Cardinal testified through its 30(b)(6) deposition designee that it was aware of the rising abuse of prescription drugs as early as 2006 when it received the first Rannazzisi letter.[19] Cardinal's former head of QRA, Steve Reardon, also testified that he was aware of the opioid epidemic in 2007.[20] Despite its awareness that opioid sales and diversion were already too high, Cardinal took no steps to reduce thresholds to address this oversupply.

When setting thresholds, Cardinal did not take into account objective measures, such as how a pharmacy's controlled substance purchases from Cardinal compared to national averages.[21] Mr. Rafalski testified that there was no evidence in the record that Cardinal monitored the overall volume of hydrocodone and/or oxycodone each distributed into Cabell-Huntington County during the relevant time frames of the available data.[22] As a result, suspiciously large orders of opioids in rural areas and smaller cities were virtually invisible to Cardinal.

Cardinal regularly permitted customers to exceed their thresholds for opioids. As a matter of policy, customers that exceeded their threshold for a particular drug could receive a certain

[18] 5/20 Trial Tr. (Moné) at 39-11; 60.

[19] Norris, 10/2/20 Depo at 142-143.

[20] Reardon, 11/30/18 Depo at 413-414.

[21] P-00080_00038.

[22] 5/26 Trial Tr. (Rafalski) at 58-59.

percentage of dosage units over the threshold once per month per drug family (e.g., an additional 10% of oxycodone). Not surprisingly, Cardinal did not put this practice in their Standard Operating Procedures (SOP), but in a document called "General Work instructions."[23]

This failure to monitor a pharmacy's actual history and instead use a national average coupled with the use of a 300% multiplier as a benchmark for an order to warrant further review permitted excessive shipments of opioids.

Simply put, it was unreasonable for Cardinal to use criteria for suspicious orders that did not take account of local population size and could not detect changes in ordering practice more gradual than a rapid 300% increase.

C. Mr. Rafalski Established that Cardinal Failed to Maintain Effective Controls Against Diversion in Cabell-Huntington

Mr. Rafalski is a former DEA diversion investigator with extensive law enforcement experience relating to the distribution of controlled substances under the Controlled Substances Act ("CSA").[24] Based on this experience, he carefully assessed Defendants' Suspicious Order Monitoring ("SOM") programs and testified to their serious flaws with regard to the maintenance of effective controls against diversion.[25]

Mr. Rafalski testified regarding six methodologies—two based on an approach endorsed by a United States Court of Appeals, and four based on systems Defendants and other distributors have used—that Cardinal could have used to identify suspicious orders (Methods A-F).[26] Applying these to Cardinal's customer and due diligence reports, Mr. Rafalski established the numbers of

[23] P-14290.

[24] *See* 5/26/21 Trial Tr. (Rafalski) at 15:24-16:5 (position at DEA was "Diversion investigator").

[25] *Id*. at 110:3-115:7.

[26] *See id.* at 84:20-85:17 (A-D); 93:22-95:21 (E-F).

orders Defendants shipped that should have been flagged as "suspicious" under the law and should have triggered due diligence investigations.[27]

This review revealed both the absence of any evidence to dispel the suspicions that were or should have been flagged, and the presence of an absurdly low number of suspicious order reports actually made by Cardinal.[28] Applying "Method B" Mr. Rafalski testified that 11,325,200, or 65.9 percent of the total dosage units for oxycodone and 7,252,580, or 40.5 percent of the dosage units of hydrocodone sent to Huntington and Cabell County should have been flagged by Cardinal as suspicious and not shipped before due diligence was conducted.[29]

Mr. Rafalski also testified that application of Methods A and C-F would have revealed even higher numbers of suspicious oxycodone and hydrocodone shipments by Cardinal.[30]

Despite the availability and acceptability of these methodologies, Mr. Rafalski testified that there was no evidence in the record that Cardinal monitored the overall volume of hydrocodone and/or oxycodone each distributed into Huntington or Cabell County during the

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[27] *See id*. at 102:4-10 (review of Defendants' due diligence and customer files); *id.* at 102:18-24 (review of Defendants' suspicious order reporting).

[28] *See id*. at 102:14-17; 104:14-105:16.

[29] *Id.* at 97-98.

[30] *See id.* at 97:1-3 (Method A – 15,997,400, or 93.1 percent of oxycodone units, and 14,795,350, or 82.5 percent of hydrocodone dosage units); *id.* at 98:20-21 (Method C - 14,011,880 or 81.5 percent of oxycodone units and 16,593,780, or 92.6 percent of hydrocodone units); *id.* at 100:6-12 (Method D - 9,567,580, or 55.7 percent of oxycodone units and 14,957,360 or 83.5 percent of hydrocodone units); *id.* at 100:25-101:2 (Method E - 13,274,080, or 77.2 percent of oxycodone units and 16,159,150, or 90.2 percent of hydrocodone units); *id.* at 101:14-17 (Method F - 16,527,880 or 96.2 percent of oxycodone units and 17,688,100, or 98 percent of hydrocodone units). Cardinal tries to brush off Mr. Rafalski's Methods C-F by claiming, incorrectly, that Mr. Rafalski disavowed four of his six methodologies on cross-examination. *See* Cardinal Health's Memo at 7 n. 11. He did no such thing. As explained in Plaintiff's Opposition to Defendants' Renewed Daubert Motion (Dkt. 1396), the portion of testimony invoked by Cardinal says nothing about the validity of Methods C through F—each of which one or more Defendant or other distributor has used a version of—as methodologies for identifying suspicious orders.

relevant time frames of the available data.[31] Mr. Rafalski's conclusion is further corroborated by Cardinal's lack of DEA reporting – ***Cardinal reported just one (1) order out of 92,915 transactions from 1996 to 2011, and 291 orders from 2013 to 2017***.[32]

Mr. Rafalski further testified that the orders Cardinal knew or should have known were suspicious were likely to be diverted into Cabell-Huntington.[33] Finally, Mr. Rafalski offers an additional opinion: based on his education, background, experience, and on his review of Cardinal's documents and conduct, including those evidencing Cardinal's lack of effective controls to prevent diversion and systemic failure to conduct due diligence, that it was more likely than not that flagged orders regarding which Cardinal did not conduct due diligence would be diverted.[34]

II. CARDINAL FAILED TO PERFORM DUE DILIGENCE ON SUSPICIOUS ORDERS AND SHIPPED ORDERS TO PHARMACY CUSTOMERS WITH KNOWLEDGE THAT THE ORDERS WERE SUSPICIOUS

But even if Cardinal had been able to detect suspicious orders it would have made no difference because its identification of orders as either excessive or suspicious had no bearing on what it decided to ship to its pharmacy customers. Without any policy to identify or block suspicious orders, the result is an inevitably inflated amount of opioids shipped across the country, including into the Cabell-Huntington area. Rather for a time, Cardinal shipped all such orders, regardless of any indicators of suspicion.

Prior to 2008 any order that exceeded Cardinal's threshold calculation was deemed excessive and simply reported to the DEA as an Excessive Order Report. Prior to 2008, there is

[31] *Id.* at 58:25-59:9.

[32] *Id.* at 104:14-105:15.

[33] *Id.* at 112-113.

[34] *Id.* at 112:22-113:6.

no evidence that Cardinal performed any due diligence on the thousands of orders identified in ILRs before they were shipped to Cardinal's customers.[35] A pharmacy could place orders deemed excessive month after month, and Cardinal would simply note the suspicious behavior and ship the drugs, no questions asked.

Even after the adoption of Cardinal's electronic suspicious order monitoring system, Cardinal continued to ship orders it knew were suspicious. From March 1, 2008 through August 31, 2009, Cardinal's SOMs was triggered 8,465 times for all shipments around the country. Of these, Cardinal only reported to the DEA 91 suspicious orders—roughly 1% of flagged orders; the balance of the orders were shipped.[36] The evidence shows that the Cardinal's due diligence programs for such review were ineffective, unenforced, and provided no meaningful safeguards that would reduce Cardinal's suspicious opioid shipments to its pharmacy customers to prevent diversion.

III. CARDINAL FAILED TO IMPLEMENT AND CARRY OUT THE DUE DILIGENCE PROGRAMS IT ADOPTED

The new electronic SOMs, which Cardinal implemented in 2008, was intended to identify potentially suspicious orders and allow Cardinal to conduct due diligence to determine whether the order should be reported to the DEA as suspicious or could be shipped.[37] Cardinal Health's policies required that the investigation be documented in the pharmacy's due diligence file.[38] Cardinal's due diligence files during the relevant time periods are practically non-existent.[39]

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[35] Brantley, 10/1/20 Depo at 367-369; Reardon, 11/30/2018 Depo at 424-428, 451-453.

[36] P-00077; P-07509; P-44267.

[37] P-00080_00014, 00019-00020.

[38] Reardon, 11/30/18 Depo at 447-448; P-14290; Norris, 10/2/20 Depo at 259-260; 5/20 Trial Tr. (Moné) at 61-62.

[39] 5/18 Trial Tr. (Rafalski) 102, 228.

As described below, Cardinal did not apply the due diligence policies it had to chain pharmacies, nor did it apply them to local pharmacies, including local pharmacies in Cabell-Huntington that received extremely high volumes of opioids. The limited utility, implementation, and enforcement of Cardinal's due diligence program meant that it was a wholly ineffective tool to identify problematic customers, stop suspicious orders, or to prevent diversion. Without an effective or meaningful due diligence program in place, Cardinal's opioid shipments remained at relentlessly high levels across the country and in Cabell/Huntington.

A. Cardinal Did Not Apply Its Due Diligence to Chain Pharmacies

Cardinal gave its chain customers special privileges. Cardinal did not calculate thresholds for chain pharmacies in the same manner as other customers; it merely applied a standard threshold for the entire chain. That meant that, regardless of a store's history of opioid orders, it would not trigger scrutiny if its volume suddenly or dramatically increased, so long as it was below the chain-wide threshold.[40]

For example, in February 2012, the DEA served an Order to Show Cause and Immediate Suspension of Registration on Cardinal's Lakeland, Florida distribution center for Cardinal's failure to conduct due diligence on its top four retail pharmacy customers, which included CVS 219 and CVS 5195 in Florida.[41] The DEA found that from January 1, 2008, through December 31, 2011, Cardinal shipped approximately 7.2 million dosage units to these two chain pharmacies.[42]

Cardinal does not have complete due diligence files for its Cabell-Huntington chain pharmacy customers. For example, there is no due diligence file for CVS 4419 of for CVS 10566.[43]

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[40] P-00080_00015.

[41] P-08873.

[42] *Id*.

[43] P-42071; P-23656.

Yet, Cardinal reported CVS 10566 to the DEA in July 2016 for a suspicious order of hydrocodone.[44] For CVS 3391, 4419, 4425, 3480, and 10566, CAH produced just 7 pages of due diligence.[45]

	Due Diligence File[46]	**Dosage Units of Oxycodone Distribution into Cabell/Huntington (2006-2014)[47]**
CVS 3391	1 page	1,543,500
CVS 4419	0 pages	1,036,000
CVS 4425	3 pages	970,200
CVS 3480	3 pages	780,000
CVS 10566	0 pages	

B. Cardinal Did Not Apply Its Due Diligence to Local Pharmacies

The evidence shows that Cardinal did not conduct due diligence with respect to local pharmacies, including Medicine Shoppe.

Cardinal increased Medicine Shoppe's threshold for oxycodone repeatedly without any due diligence associated with the threshold increase.[48] Cardinal documents show that Cardinal raised Fruth Pharmacy #5's threshold for hydrocodone from 10,000 dosage units per month to 133,000 per month with absolutely no documented due diligence to justify a thirteenfold increase in threshold.[49]

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[44] P-42071.

[45] P-23656 (Supplemental Response to Request No. 4).

[46] P-43225; P-23656 (Supplemental Response to Request No. 4).

[47] P-43225_0008-0009.

[48] P-44275 (*e.g.*, lines 249, 278, and 348); P-42116.

[49] P-44275 (lines 49 and 417); P-42101.

There is no evidence that a due diligence file ever existed for either K-Mart Pharmacy (AK8905018)[50] or ContinuumCare Pharmacy (FC1712668) in Huntington, both of which Cardinal reported to DEA for suspicious orders multiple times.[51] In the first six months of 2013, Cardinal reported 8 suspicious orders of hydrocodone placed by Fruth #5, but Fruth #5's due diligence file does not contain a single page of documentation from this timeframe.[52]

Medicine Shoppe International, Inc., is a subdivision of Cardinal that franchises and services a network of pharmacies.[53] Cardinal distributes prescription opioids to Medicine Shoppe pharmacies, including T&J Enterprises, Inc., d/b/a The Medicine Shoppe (hereafter, Medicine Shoppe), located in Huntington, West Virginia. Jesse Kave, the Cardinal salesperson assigned to the territory that included Cabell County, testified that Medicine Shoppe in Huntington was his biggest customer in the county.[54]

Cardinal reported no suspicious orders of opioids from Medicine Shoppe until 2010 and none for oxycodone until August 2012. Since 2012, Cardinal reported 66 suspicious orders of hydrocodone and 122 suspicious orders of oxycodone for Medicine Shoppe.[55]

	Oxycodone	**Hydrocodone**
2012	108	0
2013	1	61
2014	0	0
2015	1	0
2016	12	4
2017	0	1

[50] While Cardinal produced documents related to its national corporate account with K-Mart, it has not produced or identified a due diligence file for its K-Mart Pharmacy customer in Cabell County/Huntington.

[51] P-42071; P-23656 (Supplemental Response to Request No. 4).

[52] P-42071; P-42100.

[53] 5/20 Trial Tr. (Moné) at 203-204.

[54] 5/21 Trial Tr. (Kave) at 64; 77.

[55] P-42071.

2018	0	0

From November 2012 to 2018, Cardinal reported 115 suspicious orders placed by Medicine Shoppe, but after 2012 Cardinal's due diligence file for the pharmacy contains just 5 documents consisting of 18 pages.[56]

Cardinal repeatedly identified suspicious orders of opioids placed by Medicine Shoppe, shipped the orders and intentionally failed to report those orders to the DEA.[57] On February 9, 2012, Cardinal held an order placed by Medicine Shoppe for 8,000 dosage units of oxycodone because the order caused Medicine Shoppe to exceed its monthly threshold of 31,100 dosage units for oxycodone. The order was cut because, according to Cardinal Health, the "DATA [for Medicine Shoppe] DOES NOT SUPPORT QUANTITY ORDERED." The order was not reported to DEA, and QRA requested that an on-site investigation of Medicine Shoppe be conducted to determine the pharmacy's risk for diversion.[58]

Four months later, on June 12, 2012, QRA pharmacist Doug Emma emailed senior Cardinal compliance officials Linden Barber and Gilberto Quintero regarding "suspected 'hot spots', black hole cases and cases that probably need to be revisited by LV-TAC." In that context, Emma advised that Medicine Shoppe "has seen a significant growth in both areas and to my knowledge a site visit has not been conducted after submitting 6 requests to validate growth[.]".[59]

In July 2012, Doug Emma noted in an email that he had "requested a site visit multiple time on [Medicine Shoppe]" and that QRA "still need[ed] to validate the business growth and

[56] P-42116 (CAH_FEDWV_00000855, 856, 864, 871, and 878).

[57] P-14294; P-42071.

[58] P-14294 (lines 62-66); P-42071; P-42116.

[59] P-28038.

increased utilization of pain medications. Later that month, another QRA pharmacist, Janet Ng, informed Cardinal Health's Michael Moné, that "Doug Emma had requested multiple site visits since January."[60]

When a site visit was finally conducted for Medicine Shoppe on August 20, 2012, six months after the initial request, the investigation found that 1) the percentage of controlled substances prescriptions dispensed by the pharmacy was "high", 2) 71% of oxycodone dispensed in the prior three months was for 15 and 30 mg formulations, a red flag according to Mr. Kave, 3) that Cardinal saw a "disproportionate growth" of oxycodone purchases from Cardinal over the prior 12 months.[61] Eight months earlier in December 2011, Cardinal salesperson Jesse Kave notified QRA that he was informed by Medicine Shoppe's owner that he expected the pharmacy's purchase of oxycodone to decrease due to changes in prescribing patterns.[62] The site visit in August 2012 confirmed the opposite had happened.

From June to August 2012 alone, while requests for site visits went unanswered, Cardinal shipped at least 30 Medicine Shoppe orders for oxycodone or hydrocodone that it determined were suspicious but failed to report to the DEA.[63] Between 2013 and 2015, Cardinal identified at least twenty additional Medicine Shoppe orders of oxycodone or hydrocodone that were suspicious that it shipped and failed to report to DEA.[64]

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[60] P-42116.

[61] CAH-WV-000770; 5/21 Trial Tr. (Kave) at 89-94.

[62] P-42116_00063; 5/21 Trial Tr. (Kave) at 84-85.

[63] P-14294 (Column BG, lines 764, 770, 773, 777, 780, 847, 850, 853, 862, 876, 885, 929, 932, 935, 938, 941, 950, 953, 956, 959, 962, 965, 976, 987, 994, 997, 1000, 1023, 1026, and 1029); P-42071; P-42071

[64] P-42116.

Cardinal's file for Medicine Shoppe lacks any evidence of adequate due diligence in response to dozens of Medicine Shoppe orders Cardinal reported to DEA. In September 2012, Cardinal reported 33 suspicious orders for Medicine Shoppe to the DEA.[65] A review of Medicine Shoppe's due diligence file reflects a dearth of information - just a single email in September 2012 related to a single order from Medicine Shoppe with no indication the email relates to any of the 33 orders reported in September 2012.[66] This demonstrates Cardinal's ability to follow their own policies and procedures.

From August 2005 through December 2007, and in April 2008, Cardinal shipped suspicious orders of opioids to pharmacies in Cabell County that exceeded its ILR threshold amounts. The excess shipments from 259 invoiced orders contained 3,658.85 grams of opioids comprising 256,200 dosage units.[67] There is no evidence that Cardinal conducted due diligence on any of these suspicious orders prior to shipment.[68]

The following chart identifies the amount of opioid dosage units shipped to each pharmacy in excess of Cardinal's own limits from August 2005 through December 2007[69]:

Pharmacy	**Opioids (Dosage Units)**
KMART Pharmacy 5636 U.S. Route 60 E, Huntington, WV DEA #AK8905018	19,202
Med Associates Pharmacy, Inc., d/b/a Continuum Pharmacy, 78 Perry Winkle Lane, Huntington, WV DEA #BM6622167	66,031

[65] P-42071.

[66] P-42116.

[67] P-42432.

[68] P-14288; P-42432.

[69] P-42432.

Med Associates Pharmacy, Inc., dba Medical Associates #3 Chateau Lane, Barboursville, WV DEA #BM6647739	1,000
West Virginia CVS Pharmacy, LLC 505 Twentieth Street, Huntington, WV DEA #BR4301545	12,220
West Virginia CVS Pharmacy, LLC 2901 Fifth Ave., Huntington, WV DEA #BR4365486	71,036
T&J Enterprises, Inc., dba The Medicine Shoppe 2402 Adams Ave., Huntington, WV DEA #BT5541760	86,711

Many of the orders exceeded the applicable ingredient limits by large margins. For example, ten shipments to the Med Associates Pharmacy in Huntington were 1,000 to 20,000 dosage units above the relevant threshold.[70]

IV. CARDINAL DISTRIBUTED UNREASONABLE QUANTITIES OF OPIOIDS IN CABELL-HUNTINGTON

The evidence shows that Cardinal distributed unreasonable quantities of opioids to its customers in Cabell-Huntington. The evidence also shows this excessive distribution was the direct result of Cardinal's failures to detect, investigate, and halt suspicious orders in order to prevent diversion. The enormous quantities of opioids that Cardinal distributed were, moreover, clear signs that the opioids Cardinal was selling were being diverted. There were simply not enough people

[70] P-14288; P-42432.

living the Cabell-Huntington community for the quantity of opioids to be used exclusively for legitimate purposes.

Between January 1996 and May 2018, Cardinal distributed over 37 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell-Huntington, a community of 100,000 people.[71]

Between 2006 and 2014, Cardinal's monthly average shipments of oxycodone to Cabell-Huntington chain and retail pharmacies was 6,989 dosage units compared to its national average of 4,975 dosage units.[72] In January 2006, Cardinal Health's average shipments of oxycodone to Cabell-Huntington chain and retail pharmacies was 5,120 dosage units compared to its national average of 3,414 – a ratio of approximately 1.5.[73] By April 2010, Cardinal Health's average shipments of oxycodone to Cabell-Huntington had reached 8,559 dosage units compared to its national average of 4,876 dosage units – a ratio of approximately 1.8.[74]

Cardinal Health's three times threshold multiplier meant that orders that should have raised suspicions would not be detected by the Order Monitoring Program ("OMP").

From January 2006 through December 2014, Cardinal Health's average dosage units shipped to Medicine Shoppe in Cabell-Huntington was 18,644 – 3.7 times Cardinal's national average.[75] During January 2006, Cardinal Health's national average sales of oxycodone were 3,414 a month.[76] During that same month, Cardinal shipped 10,400 dosage units to Medicine Shoppe in

[71] P-44711_00024.

[72] P-43225_00007; 5/10 Trial Tr. (McCann) at 132.

[73] P-43225_00007 at #1; 5/10 Trial Tr. (McCann) at 132.

[74] P-43225_00007 at #52; 5/10 Trial Tr. (McCann) at 132-133.

[75] P-43225_00007; 5/10 Trial Tr. (McCann) at 133.

[76] P-43225_00007 at #1.

Cabell-Huntington.[77] The shipments of oxycodone from Cardinal to the Medicine Shoppe increased over the years reaching a peak of 34,600 dosage units in November 2010 compared to Cardinal Health's national average of 5,074.[78] Between January 2006 and December 2014, Cardinal sold and shipped 2,013,500 dosage units of oxycodone to the Medicine Shoppe in Cabell-Huntington.[79]

From January 2006 through December 2014, Cardinal Health's average dosage units shipped to CVS #03391 in Cabell-Huntington was 14,292 – almost 3 times Cardinal's national average.[80] During January 2006, Cardinal shipped 7,800 dosage units to CVS #03391in Cabell-Huntington.[81] The shipments of oxycodone from Cardinal to the CVS #03391 increased over the years reaching a peak of 24,600 dosage units in March 2010 compared to Cardinal Health's national average of 5,283.[82] Between January 2006 and December 2014, Cardinal sold and shipped 1,543,500 dosage units of oxycodone to CVS #03391 in Cabell-Huntington.[83]

From January 2006 through December 2014, Cardinal Health's average dosage units shipped to CVS #04419 in Cabell-Huntington was 9,593.[84] During January 2006, Cardinal shipped 8,100 dosage units to CVS #04419 in Cabell-Huntington.[85] The shipments of oxycodone from Cardinal to the CVS #03391 increased over the years reaching a peak of 16,600 dosage units in

[77] P-43225_00007 at #1.

[78] P-43225_00008 at # 59.

[79] P-43225_00007.

[80] P-43225_00007; 5/10 Trial Tr. (McCann) at 134.

[81] P-43225_00007 at #1.

[82] P-43225_00007 at # 51.

[83] P-43225_00007.

[84] P-43225_00007.

[85] P-43225_00007 at #1.

December 2013 compared to Cardinal Health's national average of 6,925.[86] Between January 2006 and December 2014, Cardinal sold and shipped 1,036,000 dosage units of oxycodone to CVS #4419 in Cabell-Huntington.[87]

From January 2006 through December 2014, Cardinal Health's average dosage units shipped to CVS #04425 in Cabell-Huntington was 8,983.[88] During January 2006, Cardinal shipped 8,100 dosage units to CVS #04425 in Cabell-Huntington.[89] The shipments of oxycodone from Cardinal to the CVS #04425 increased over the years reaching a peak of 14,500 dosage units in November 2010 compared to Cardinal Health's national average of 5,074.[90] Between January 2006 and December 2014, Cardinal sold and shipped 970,200 dosage units of oxycodone to CVS #04425 in Cabell-Huntington.[91]

From January 2006 through December 2014, Cardinal Health's average dosage units shipped to CVS #03480 in Cabell-Huntington was 7,290.[92] During January 2006, Cardinal shipped 7,290 dosage units to CVS #03480 in Cabell-Huntington.[93] The shipments of oxycodone from Cardinal to the CVS #03480 increased over the years reaching a peak of 16,700 dosage units in July 2014 compared to Cardinal Health's national average of 6,827.[94] Between January 2006 and

[86] P-43225_00008 at # 96.

[87] P-43225_00007.

[88] P-43225_00007.

[89] P-43225_00007 at #1.

[90] P-43225_00008 at # 59.

[91] P-43225_00007.

[92] P-43225_00007.

[93] P-43225_00007 at #1.

[94] P-43225_00008 at # 103.

December 2014, Cardinal sold and shipped 780,000 dosage units of oxycodone to CVS #03480 in Cabell-Huntington.[95]

From January 2010 through December 2014, Cardinal Health's average dosage units shipped to Fruth #12 in Cabell-Huntington was 8,162.[96] During January 2010, Cardinal shipped 5,000 dosage units to Fruth #12 in Cabell-Huntington.[97] The shipments of oxycodone from Cardinal to the Fruth #12 increased over time reaching a peak of 12,000 dosage units in June 2010 compared to Cardinal Health's national average of 5,183.[98] Between January 2010 and December 2014, Cardinal sold and shipped 489,700 dosage units of oxycodone to Fruth #12 in Cabell-Huntington.[99]

From January 2010 through December 2014, Cardinal Health's average dosage units shipped to Fruth # 5 in Cabell-Huntington was 8,109.[100] During January 2010, Cardinal shipped 14,200 dosage units to Fruth #5 in Cabell-Huntington.[101] Between January 2010 and December 2014, Cardinal sold and shipped 486,560 dosage units of oxycodone to Fruth #5 in Cabell-Huntington.[102]

The numbers for Cardinal Health's sales of hydrocodone to the local Cabell-Huntington pharmacies follow a similar magnitude both in gross numbers and compared to the national

[95] P-43225_00007.

[96] P-43225_00007.

[97] P-43225_00007 at #49.

[98] P-43225_00008 at # 54.

[99] P-43225_00007.

[100] P-43225_00007.

[101] P-43225_00007 at #49.

[102] P-43225_00007.

average.[103] The total quantity of opioids Cardinal shipped into Cabell-Huntington month after month could not have been reasonable.

V. CARDINAL KNEW THAT ITS ANTI-DIVERSION PROGRAMS WERE INADEQUATE, AND KNEW THE DEVASTATING EFFECTS OF THE FAILURE TO MAINTAIN CONTROLS AGAINST DIVERSION, BUT FAILED TO MAKE CHANGES

A. The DEA Told Cardinal About Flaws in Its Program, But Cardinal Consistently Ignored this Regulatory Guidance

The evidence elicited at trial shows that the DEA communicated specific flaws in Cardinal's diversion control programs throughout the years. The DEA's Distributor Initiative Meetings, "Dear Registrant" Letters sent to Cardinal, and enforcement actions against Cardinal all provided bright line guidance related to Cardinal's regulatory obligations and responsibilities to maintain effective controls to prevent diversion. Cardinal's response to this guidance was to continue to maximize profits through excessive levels of opioid shipments to its customers. Cardinal's failures, over the course of years, to heed the DEA's consistent message about the failures of its diversion control programs demonstrates the unreasonableness of Cardinal's conduct with respect to the distribution of opioids.

1. The DEA Did Not Approve Diversion Control Programs

Cardinal attempts to justify sidestepping the DEA's guidance by arguing the DEA had approved and accepted reporting of excessive orders (including orders that were reported after they were shipped) and AmerisourceBergen's suspicious order monitoring system which Cardinal implemented.[104] Plaintiffs' incorporate Plaintiffs' Response to AmerisourceBergen Drug Corporation's Memorandum in Support of Motion for Judgment Under Rule 52(c) Based on

[103] P-43225_00010-00012.

[104] Dkt. 1453 at 3.

Plaintiffs' Failure to Prove Culpable Conduct – Evidence §VI.A.1 which details how the DEA does not approve or endorse diversion control programs.

2. The 2005 Distributor Initiative Meeting Provided Regulatory Guidance to Cardinal that Cardinal Ignored

In 2005, Cardinal attended a meeting with the DEA in which the DEA provided specific guidance to Cardinal on its regulatory obligations and responsibilities to maintain effective controls against diversion.[105] Plaintiffs incorporate Plaintiffs' Response to AmerisourceBergen Drug Corporation's Memorandum in Support of Motion for Judgment Under Rule 52(c) Based on Plaintiffs' Failure to Prove Culpable Conduct – Evidence §VI.A.3 in regard to the testimony and content of the DEA's Distributor Initiative Meetings and PowerPoint presentation.

3. The "Dear Registrant" Letters Provided Regulatory Guidance to Cardinal that Cardinal Ignored

During 2006 and 2007, the DEA sent three letters to registrants across the country, including Cardinal, outlining its legal obligations to conduct due diligence, report suspicious orders, and avoid filling suspicious orders.[106] Plaintiffs incorporate Plaintiffs' Response to AmerisourceBergen Drug Corporation's Memorandum in Support of Motion for Judgment Under Rule 52(c) Based on Plaintiffs' Failure to Prove Culpable Conduct – Evidence §VI.A.4 in regard to the testimony and content of the DEA's "Dear Registrant" letters.

CAH received the first Rannazzisi letter in September 2006, and Cardinal, as well as it's then head of QRA Steve Reardon, understood that the letter informed Cardinal of a duty to stop

[105] *See* P-09114, 6/7 Trial Tr. (Rannazzisi) at 200.

[106] P-00032; 6/8 Trial Tr. (Rannazzisi) at 115-16.

shipment of suspicious orders.[107] Mr. Reardon testified that he understood the letter and would have asked DEA questions if he had not.[108]

Cardinal has understood since receipt of the 2006 letter that the practice of shipping suspicious orders was not compliant with the Controlled Substances Act.[109] However, CAH failed to implement any policy to stop shipments of suspicious orders until at least 2008, and Cardinal, through its 30(b) designee Jennifer Norris, testified that it had no knowledge of when it first took action to implement such a policy following receipt of the 2006 letter.[110] As noted above, Cardinal routinely allowed customers to exceed their thresholds and focused on "suspicious customers" as opposed to suspicious orders.

Cardinal's decision to ignore the clear and repeated regulatory guidance of the "Dear Registrant" Letters is indefensible. When provided specific and concrete information as to the critical flaws of its SOM system, it simply buried its head in the sand. The result is an intentionally weakened and toothless SOM system which fell far short of what the DEA considered to be effective controls to prevent diversion. Such a weakened and toothless system accordingly played no meaningful role in reducing Cardinal's overall shipping volume throughout the country.

4. The DEA Issued 4 Orders to Show Cause to Cardinal Which Further Put Cardinal On Notice that Its Systems Were Inadequate to Maintain Effective Controls to Prevent Diversion

In a clear signal that Cardinal's SOM system failed to maintain effective controls to prevent diversion, between November 2007 and January 2008, the DEA issued four Orders to Show Cause to Cardinal distribution centers in Washington, Florida, New Jersey and Texas, asserting that

[107] Reardon, 11/30/18 Depo at 419-420; Norris, 10/2/20 Depo at 135-135.

[108] Reardon, 11/30/18 Depo at 419-420.

[109] Norris, 10/2/20 Depo at 172.

[110] Norris, 10/2/20 Depo at 292-295.

Cardinal failed to maintain effective controls to prevent diversion, distributed to customers it knew or should have known were diverting opioids, and Cardinal did not have adequate policies and procedures in place to detect and prevent diversion. With respect to Cardinal's distribution center in Lakeland, Florida, DEA alleged that from August 2005 to October 2007, Cardinal distributed more than 8 million dosage units to customers it knew or should have known were diverting opioids.[111]

Cardinal entered into MOAs and settlements with the DEA in 2008, 2012, and 2016 that put the company on notices that its SOMs was inadequate. In its 2012 MOA with the DEA, related to Cardinal's distribution of excessive amounts of oxycodone to retail pharmacies, including some chain pharmacies, Cardinal admitted "its due diligence efforts for some pharmacy customers and its compliance with the 2008 MOA, in certain respects, were inadequate." The DEA testified that it was "frustrated that registrants were blatantly violating the MOUs[/MOAs] from prior administrative actions" including "Cardinal Health's 2008 MO[A] and settlement which resulted in a second DEA fine." Again in 2016, Cardinal entered a MOA with the DEA acknowledging its failure, from January 2009 until May 2012, "to comply with regulations requiring reports of pharmacies' suspicious orders of certain narcotic medications."[112]

After Cardinal entered into the 2012 MOA with DEA, Cardinal was served with a shareholder's demand letter alleging the company failed to implement systems to detect and prevent the diversion of controlled substances. P-00080. In response, Cardinal's Board of Directors appointed a "Special Demand Committee" to investigate the shareholder's claims. Id. The

[111] P-08873.

[112] P-08873; P-02037; Prevoznik Dep., 4/18/2019 Depo at 621.

committee drafted a report detailing Cardinal Health's failures related to the implementation and effectiveness of Cardinal's SOMS until 2012. *Id.*

Cardinal demoted two of its compliance executives in connection with the 2012 ISO and MOA. Steve Morse was removed as Director of Investigations for failing to timely terminate pharmacy customers despite finding evidence of suspected diversion. The Special Demand Committee's report cited Morse's questionable judgment and the fact that he failed to review pharmacy site visit reports as required by Cardinal's 2008 SOPs. Similarly, Michael Moné was moved from his position as Vice President of Anti-Diversion into a position as an attorney with the company's regulatory group. The Special Demand Committee report states that Mr. Moné was moved as part of Cardinal's transition to "assessing customers based more on objective criteria."[113]

B. Cardinal Was Aware of the Devastating Effects of Its Failure to Maintain Effective Controls Against Diversion

Cardinal has been well aware of the problems of opioid abuse and diversion and the ongoing epidemic for years, further demonstrating the unreasonableness of its conduct. Mr. Moné admitted that he knew the country was facing a public health crisis related to the use of opioids in 2007.[114] Cardinal testified through its 30(b)(6) deposition designee that it was aware of the rising abuse of prescription drugs as early as 2006 when it received the first Rannazzisi letter.[115] Cardinal's former head of QRA, Steve Reardon, also testified that he was aware of the opioid epidemic in 2007.[116] Cardinal knew that migration of pills was a known concern.[117]

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[113] P-00080_00037-00038.

[114] 5/20 Trial Tr. (Moné) at 79.

[115] Norris, 10/2/20 Depo at 142-143.

[116] Reardon, 11/30/18 Depo at 413-414.

[117] 5/20 Trial Tr. (Moné) at 113.

By 2001 the United States Department of Justice ("DOJ") issued a warning about widespread diversion of Oxycontin and in 2003 the federal Government Accountability Office ("GAO") issued a report on the same subject, Prescription Drugs: Oxycontin Abuse and Diversion and Efforts to Address the Problem.

VI. THE EVIDENCE SHOWS THAT CARDINAL'S DISTRIBUTION OF OPIOIDS INTO CABELL-HUNTINGTON VIOLATED THE CSA AND THE REQUIREMENT THAT CARDINAL PROVIDE "EFFECTIVE CONTROLS" AGAINST DIVERSION

The CSA requires distributors like Cardinal to design and operate a system to identify suspicious orders of controlled substances (the "identification duty"); to report to the DEA suspicious orders when discovered (the "reporting duty"); and to decline to ship an order identified as suspicious unless and until, through due diligence, the registrant is able to determine that the order is not likely to be diverted into illegal channels (the "no-shipping duty").[118] The CSA defines suspicious orders to include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[119]

The evidence shows that Cardinal shipped suspicious orders of opioid products without conducting due diligence. Until 2008, Cardinal relied on excessive order reports to identify and report suspicious orders. These excessive orders were generated after the orders had already been shipped. The generation of these after-the-fact reports made it impossible for Cardinal to comply with the no-shipping duty. Because the identified orders had already been shipped to their

[118] *See* 21 C.F.R. § 1301.74; *In re Nat'l Prescription Opiate Litig*., 1:17-md-02804-DAP, 2019 WL 3917575 (N.D. Ohio Aug. 19, 2019); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, 861 F.3d 206, 212-213 (D.C. Cir. 2017); *see also Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007).

[119] 21 C.F.R. § 1301.74(b).

respective customers, it would have been impossible to conduct any due diligence on the orders identified on the excessive order reports prior to shipping.

Cardinal did not have a policy to stop shipment of suspicious orders until 2008. As evidence by the sheer volume of opioids Cardinal sent to local pharmacies, even after adopting its so-called enhanced diversion control program in 2008, Cardinal continued to ship and distribute excessive amounts of opioids into Cabell-Huntington. Cardinal set artificially high thresholds, continually shipped orders in excess of thresholds, failed to conduct due diligence and failed to maintain documentation that it conducted due diligence.

ARGUMENT

I. UNREASONABLE INTERFERENCE WITH A PUBLIC RIGHT CONSTITUTES A PUBLIC NUISANCE

West Virginia has adopted the definition of "public nuisance" set forth in § 821B of the Restatement (Second) of Torts ("Restatement"):[120] "A public nuisance is an unreasonable interference with a right common to the general public."[121] Thus, in West Virginia, the touchstone of public nuisance liability is unreasonableness.[122]

Both this Court and the Defendants recognize that unreasonableness is the applicable standard. This Court so held in its Memorandum Opinion and Order denying Defendants' motion

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[120] *See Duff v. Morgantown Energy Assocs. (M.E.A.)*, 421 S.E.2d 253, 257 n.6 (W. Va. 1992); *Sharon Steel Corp. v. City of Fairmont*, 334 S.E.2d 616, 620 (W. Va. 1985); *State ex rel. Morrisey v. AmerisourceBergen Drug Corp.*, No. 12-C-141, 2014 WL 12814021, at *9 (W. Va. Cir. Ct. Dec. 12, 2014); *Rhodes v. E.I. du Pont de Nemours and Company*, 657 F.Supp.2d 751, 768 (S.D. W.Va. 2009); *Barker v. Naik,* No. 2:17-CV-04387, 2018 WL 3824376, at *3 (S.D.W. Va. Aug. 10, 2018) (Johnston, C.J.); see also *Callihan v. Surnaik Holdings of WV, LLC*, No. 2:17-CV-04386, 2018 WL 6313012, at *5 (S.D.W. Va. Dec. 3, 2018).

[121] RESTATEMENT § 821B(1) (1979).

[122] *See, e.g., Duff*, 421 S.E.2d at 262 (reasonableness of conduct determines whether conduct constitutes a nuisance); *West v. National Mines Corp.*, 285 S.E.2d 670 (W. Va. 1981), *reh'g on appeal*, 336 S.E.2d 190 (W. Va. 1985) (activity must be reasonable to avoid liability for nuisance).

for summary judgment regarding fault.[123] For the purposes of this motion, the Defendants have conceded that unreasonableness is the standard based on this ruling.[124] The evidence at trial establishes that Plaintiffs have met this burden.

II. PLAINTIFF HAVE PROVEN THAT CARDINAL UNREASONABLY INTERFERED WITH A PUBLIC RIGHT

As described above, the evidence shows that Cardinal's conduct was unreasonable in multiple ways. The conduct in question is the distribution of dangerously addictive narcotics with a high risk of diversion. Distributors like Cardinal are uniquely able to act to prevent diversion because they know the quantity of opioids they are shipping to their customers within a particular region and can observe patterns of excessive or unusual ordering indicative of diversion at the pharmacies they supply. Nonetheless, Cardinal acted unreasonably in failing to control the supply

[123] *See* April 29, 2021 Memorandum Opinion and Order, Dkt. 1294 at 6 (finding "Defendants have not established that there is a 'fault' element (in the way they describe it [intent, recklessness, or negligence]) of a public nuisance claim under West Virginia law."); *id.* ("The court agrees with plaintiffs that because defendants' motion does not establish the reasonableness of defendants' conduct, the motion should be denied.").

[124] ABDC's Brief at 6-7; Cardinal Brief at 5, n8; and McKesson Brief at 5. Even assuming arguendo that the Defendants are correct that an element of "fault" is required to prove the unreasonableness of their conduct, Dkt. 1294 at 6, the Plaintiffs have met the requirement as Defendants' conduct was intentional. In denying the Defendants' motions for summary judgment pertaining to fault, this Court held that "even assuming that there is a culpability ("fault") element in the public nuisance context, the motion should still be denied because there are disputed issues of material fact about whether defendants' conduct was intentional." Dkt. 1294 at 6 As the Court noted, Plaintiffs are not required to prove mens rea – or intent to create the opioid crisis or the resulting harms – only that their actions were intentional. Dkt. 1294 at 5-6. Here, the Plaintiffs proved that Cardinal's conduct was an unreasonable interference based on its intentional selling and shipment of high volumes of opioids into Cabell-Huntington. Cardinal attempts to relitigate this Court's ruling and argues this Court misread *Hendricks v. Stalnaker*, 380 S.E.2d 198 (W. Va. 19889) (*see* Dkt 1453, n.8, Appendix A – Tab 21). Plaintiffs disagree and believes this Court correctly distinguished *Hendricks* and rightly concluded that *Hendricks* contradicts Cardinal's definition of intentional conduct. Dkt. 1294 at 4-6. *See also* Dkt. 1075 (Plaintiffs' Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims).

of opioids into Cabell-Huntington and failing to take reasonable steps to prevent diversion of these dangerous drugs.

Cardinal acted unreasonably when it distributed an unreasonable quantity of opioids into Cabell and Huntington taking account of the size of the population of the area into which these drugs were shipped and the scourge of addiction that emerged. It also acted unreasonably in operating its SOM programs: first, because the programs were not designed to detect suspicious orders at risk of being diverted; second, because the programs did not prevent Cardinal from shipping orders it knew to be at risk of diversion; third because Cardinal did not follow the programs it adopted, and fourth because Cardinal knew about the harm its excessive shipments was causing and was repeatedly told what it needed to do in order to operate a proper SOMs program, but repeatedly failed to heed the guidance it was given. Finally, Cardinal acted unreasonably with respect to the distribution of opioids when it failed to comply with the requirements of the CSA.

A. The Volume of Pills Shipped to Cabell and Huntington Proves Unreasonable Conduct

Cardinal's distribution of an extraordinarily disproportionate quantity of opioids into Cabell and Huntington was unreasonable.[125]

Cardinal distributed over 37 million dosage units of hydrocodone and oxycodone to pharmacies in Cabell-Huntington, between January 1996 and May 2018, the equivalent of 370 doses for every man, woman, and child in the community, an amount that was, in and of itself, unreasonable and could not be explained by changes in the standard of care for treating pain.[126]

[125] *See* The Evidence, § IV, *supra*.

[126] P-44711_00024.

Despite Cardinal's knowledge of the opioid crisis dating back to 2007, Cardinal distributed increasingly large amounts of opioids into Cabell-Huntington.[127] The vast volume of opioids Cardinal supplied to pharmacies in Cabell-Huntington should have put it on notice that it was not supplying a legitimate market for the drugs.[128] It was not only the overall volume of opioids they shipped to Cabell-Huntington, but the volume they sold to particular pharmacies that could only have been regarded as pill mills that should have alerted Cardinal that they were fueling diversion.

Huntington had a census population of 49,138 in 2010.[129] Between January 2006 and December 2014, Cardinal sold and shipped 2,013,500 dosage units of oxycodone to the Medicine Shoppe in Cabell-Huntington – about 41 doses for every man, woman, and child in the city – from a single pharmacy.[130]

Yet, though Mr. Rannazzisi testified – and common-sense dictates – that distributors should consider the volume of opioids it sells to a customer or area relative to its population, Cardinal neither weighed these factors, or even totaled its shipments of opioids into a jurisdiction, in assessing whether orders were suspicious or diversion might be occurring.[131]

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[127] *See supra*, Evidence §§ IV and V.B, *supra*.

[128] Plaintiffs incorporate Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Judgment on Partial Findings on Causation, Doc. No. 1469, §II.B.1 (Foreseeability of Diversion).

[129] ECF No. 1433-7.

[130] P-43225_00007.

[131] 6/8 Trial Tr. (Rannazzisi) at 186 ("what we asked them to do is look at your suspicious – your pharmacy population, your customer population, identify anomalies within that population, ordering patterns, and then do your due diligence and see why those anomalies exist"); Prevoznik, 5/17/19 Depo at 974 (DEA had said that knowledge of a geographic area's problem with controlled substance abuse is a factor that should be taken into account by registrants); *see also See* 5/26/21 Trial Tr. (Rafalski) at 112 (orders the Defendants knew or should have known were suspicious were likely to be diverted into the illicit market).

These figures actually undercount the volume of opioids that reached Huntington and Cabell County. As detailed by James Rafalski, an additional wave of opioids were making their way into West Virginia from Florida and other states via a route often referred to as the "Oxy Express" or "Blue Highway."[132] Cardinal Health's failure to maintain effective controls against diversion, as demonstrated by its failure to conduct due diligence and practice of unjustifiably raising thresholds resulted in an onslaught of pills into Cabell-Huntington as evidenced by the sheer volume of pills it sent to the local pharmacies.[133]

B. The Evidence Relating to Cardinal Health's Diversion Control Program Establishes Unreasonable Conduct

As discussed in detail above, key deficiencies marred each of Cardinal's diversion control programs. Cardinal's diversion control programs were carried out nationally, through centralized compliance staff.

Cardinal's programs for detecting "suspicious orders" of prescription opioids was not designed to, and could not, detect a significant percentage of orders that were sufficiently unusual in volume, pattern, or frequency to be indicative of diversion.[134] Cardinal depended on monthly, volume-based thresholds for pharmacy customers as triggers for identifying potentially suspicious orders. By the time Cardinal put thresholds in place, opioid sales and, thus, customer purchasing baselines had already been inflated by nearly a decade of diversion and excessive sales. Therefore, they were set too high, and offered no meaningful brake on suspicious orders. Cardinal's

[132] 5/27 Trial Tr. (Rafalski) at 151-152 ("people that would get on airplanes in Huntington and fly to Florida to go to the pain clinics to get pills and then come back"; "Allegiant flight that was – they called it the Pill Express"); Mash, 7/28/2020 Depo at 81-82 (had heard of the Oxy Express coming from Florida through West Virginia); 5/13 Trial Tr. (Zimmerman) at 90-91.

[133] *See supra* Evidence § IV.

[134] *See* The Evidence, §I, *supra*.

unjustifiably high thresholds meant that threshold events and reported suspicious orders were relatively rare. Cardinal focused on reporting "suspicious customers" and rarely reported suspicious orders.

Cardinal failed to perform due diligence on opioid orders it knew were suspicious to determine if diversion was likely, shipped orders of prescription opioids it knew were suspicious without first ascertaining that those orders were not likely to be diverted, and continued shipping opioids to pharmacies that it knew showed indicia of diversion.[135]

Cardinal failed to properly implement the anti-diversion programs that it did have.[136] Prior to 2008, Cardinal Health's anti-diversion staff was operating without sufficient resources or personnel. Cardinal granted special privileges to its chain pharmacy customers applying a standard threshold for the entire chain. This policy permitted an individual store to avoid scrutiny if its volume suddenly or dramatically increased so long as it was below the chain-wide threshold. Additionally, Cardinal regularly permitted customers to exceed their thresholds for opioids.

Cardinal knew that its anti-diversion programs were inadequate, and knew the devastating effects of the failure to maintain controls against diversion, but failed to make changes to address the inadequacies.[137]

Mr. Rafalski testified that Cardinal's systemic failures to maintain effective controls were a substantial factor in the diversion of prescription opioids into Cabell-Huntington.[138] He further

[135] *See* The Evidence, §II, *supra*.

[136] *See* The Evidence, §III, *supra*.

[137] *See* The Evidence, §V, *supra*.

[138] *See* The Evidence, §I.C, *supra*.

testified that the orders Cardinal knew or should have known were suspicious were likely to be diverted into Cabell-Huntington.[139]

As set forth in detail above, the failure of Cardinal Health's national, systemic diversion control program was laid bare by Cardinal repeatedly increasing the thresholds of its local customers without any due diligence associated with the threshold increase. The failure is further evidenced by Cardinal Health's repeated identification of suspicious orders made by its local customer Medicine Shoppe, and the decisions to ship those orders.

C. CARDINAL'S CONDUCT WAS UNREASONABLE BECAUSE IT VIOLATED THE CSA

Cardinal adopted by reference ABDC's argument that the Plaintiffs cannot prove actionable conduct against Defendants based on alleged violations of the federal or West Virginia Controlled Substances Acts. Plaintiffs incorporate Plaintiffs' Response to AmerisourceBergen Drug Corporation's Memorandum in Support of Motion for Judgment Under Rule 52(c) Argument § II.C.

The evidence presented at trial and outlined throughout this brief establishes that Cardinal clearly violated the CSA and WV CSA.[140] The volume of opioids shipped by Cardinal, the lack of controls to identify and stop suspicious orders, and their intentional disregard of what few procedures they had to protect the public each clearly establish statutory and regulatory violations. Such violations of the law are sufficient to allow the Court to conclude that Cardinal acted unreasonably.

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[139] *Id*.

[140] *See* The Evidence, §VII, *supra*.

III. MR. RAFALSKI'S TESTIMONY CONSIDERED CONTEXT AND HIS OPINIONS ARE NOT CONCLUSORY, BUT ARE BASED ON HIS EXPERIENCE AS A DEA INVESTIGATOR AND A REVIEW OF CARDINAL HEALTH'S POLICIES AND PROCEDURES

Cardinal first contends that Mr. Rafalski failed to consider context, and that there is a contradiction between Mr. Rafalski's purported opinion that a large proportion of suspicious orders were diverted and the important role of over-prescribing in the opioid epidemic. To begin with, Mr. Rafalski is not expressing an opinion on the number of suspicious orders that were actually diverted. More importantly, there is nothing contradictory about identifying both diversion and over-prescribing as causes of the opioid epidemic.[141] Indeed, Plaintiffs demonstrate that the two causes operated simultaneously, with over-prescribing and diversion-control failures *both* leading to increased opioids in Plaintiffs' communities.[142] In their capacity as registrants under the CSA, Cardinal specifically was charged with maintaining effective controls against diversion, which it did not.

Cherry-picking excerpts from Mr. Rafalski's trial testimony, Cardinal next argues that his opinions concerning the deficiencies in its SOMs and due diligence policies are "rote" and "conclusory." Cardinal is wrong. Mr. Rafalski provides an appropriate, and well-accepted basis for assessing the extent to which Cardinal shipped suspicious opioid orders to Huntington and Cabell County.

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[141] *See*, *e.g.*, *City and County of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 683 (N.D. Cal. 2020) (rejecting Distributors' argument for dismissal based on standard of care, holding that "Manufacturers' alleged false marketing and Defendants' alleged failure to maintain effective controls to prevent diversion are both independent causes of the City's harm."); *see generally Wehner v. Weinstein*, 191 W. Va. 149, 155, 444 S.E.2d 27, 33 (1994) ("We long have recognized the doctrine of concurrent negligence . . . .").

[142] *See* Plaintiffs' Memorandum of Law in Opposition to Defendants' Motions for Judgment on Partial Findings on Causation at § I.B. (Defendants' Causation Arguments Based on Prescribing Standards Ignore Their Own Diversion-Control Failures as Concurrent Causes of the Nuisance Harms in Cabell and Huntington (Dkt. 1469)).

Cardinal's Pre-2007 Policy—Mr. Rafalski testified that Cardinal's pre-2007 policy consisted of an "ingredient limit" in which four times the average of the past twelve months was considered as a suspicious order that required due diligence before shipping.[143] Mr. Rafalski's testimony reveals, however, that this woefully insufficient system failed to identify, stop, and report suspicious orders, causing millions of opioid pills to flood Cabell and Huntington County during the relevant time periods.[144]

Relatedly, Cardinal also argues that their pre-2007 policy was adequate because the DEA had not articulated a "no shipping duty" until "2006 or 2007." But the no-shipping duty is nothing more than an implementation of the basic duty to "maintain effective controls against diversion."[145] Put another way, there can be no "effective controls against diversion" if a registrant is permitted to ship opioid orders it knows or should know bear the indicia of likely diversion. Thus, the no-shipping duty is not a later addition to the CSA or the regulations, but part and parcel of the original enactment. It is an "interpretive rule," which, rather than creating new duties, "simply states what the [administrative agency] thinks the statute means, and only reminds affected parties of existing duties. . . ."[146]

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[143] *See* 5/26/21 Trial Tr. (Rafalski) at 68:1-10.

[144] *See id.* at 45:13-14; 46:3-11; 56:10-16 (reviewing an extended period of transactional data [1996-2018] for Cardinal); *id.* at 42:10-23 (basing his testimony, in part, on the "the Suspicious Order Monitoring Systems for [Cardinal] during the timeline of the investigation"); *id*. at 108:3-14 (finding that Cardinal failed to maintain effective control to prevent diversion of prescription opioids into the illicit market in Huntington and Cabell County); 59:3-5 (finding no "evidence that the defendants monitored the overall volume of hydrocodone and/or oxycodone each distributed into Huntington-Cabell County, West Virginia during the time frames of the available data."); 72:3-7; 73:2-4 (testifying that Cardinal shipped suspicious orders before reporting them to the DEA).

[145] *Southwood Pharmaceuticals, Inc.; Revocation of Registration*, 72 FR 36487-01, 36500, 2007 WL 1886484 (DEA July 3, 2007).

[146] *Minuto v. Wendt*, 2005 WL 1330539, at *4 (N.D. W.Va. May 3, 2005), aff'd, 182 F. App'x 245 (4th Cir. 2006) (internal citations omitted).

Indeed, the 2007 *Southwood Pharmaceutical* proceedings confirm this is so: if the duty had not already existed, *Southwood* would not have lost its registration for failing to comply with it.[147] Judge Polster has found similarly:

> [T]he Court is hard-pressed to think of a more basic requirement than not to ship a dubious order bearing indicia that the drugs could be diverted to illegal channels. How can a registrant freely ship suspicious orders and still comply with its duty to maintain controls against diversion? It cannot. It has a duty not to ship the order unless due diligence reasonably dispels the suspicion.[148]

Cardinal's Post-2007 Policy—Mr. Rafalski testified that he reviewed all three iterations of Cardinal's SOMs systems, including "a change around the 2007-2008 time period."[149] Based on this assessment—and consistent with his testimony on Cardinal's pre-2007 policy—Mr. Rafalski found that Cardinal failed to maintain effective control to prevent diversion of prescription opioids into the illicit market in Huntington and Cabell County.[150] He further testified that the orders Defendants knew or should have known were suspicious were likely to be diverted into the illicit market in Huntington and Cabell County.[151] These systemic failures "were a substantial factor in the diversion of prescription opioids into the illicit market in Huntington-Cabell County."[152]

Cardinal criticizes Mr. Rafalski for failing to review and testify on specific suspicious orders. This type of review is simply not necessary. Mr. Rafalski's testimony makes clear that in

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[147] *See* FR 36487-01, 36498-502, 2007 WL 1886484.

[148] *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3917575, at *9 (N.D. Ohio Aug. 19, 2019); *see also City and County of San Francisco*, 491 F. Supp. 3d at 632 (adopting MDL Court's conclusions on no-shipping duty).

[149] *See* 5/26/21 Trial Tr. (Rafalski) at 57-58.

[150] *Id*. at 108.

[151] *Id.* at 112-113.

[152] *Id.* at 111-112.

his opinion the metric identified in *Masters* is a reasonable estimate and an initial trigger and first step for identifying orders of unusual size.[153] Thus, the opinion Mr. Rafalski is offering is that, consistent with the *Masters* decision, Cardinal was obligated to investigate all suspicious orders prior to shipping them. Cardinal failed to adequately identify suspicious orders and to do the requisite investigation prior to shipping.[154] Given the focus of his testimony—Defendants' (including Cardinal's) systemic failure to identify suspicious orders and conduct adequate due diligence in the first place—there was no reason for Mr. Rafalski to review each order separately to determine whether a specific order was in fact suspicious and should not have been shipped.

Cardinal also attacks Mr. Rafalski's opinion that they did not perform due diligence as "lack[ing] credibility and heft."[155] It does not. This conclusion that the absence of documentation means an absence of due diligence is precisely the type of opinion that Mr. Rafalski's experience as a DEA Diversion Investigator qualifies him to make. This conclusion finds further support in the D.C. Circuit's *Masters* opinion:

> As the Administrator noted, the lack of documentation was evidence that the [customer due diligence] phone calls never took place: 'The *absence of an entry* [in business records], where an entry would naturally have been made if a transaction had occurred, should ordinarily be equivalent to an assertion that no such transaction occurred, and therefore should be admissible in evidence for that purpose.[156]

Mr. Rafalski's conclusion that the absence of documentation means an absence of due diligence is further supported by the documentation that did exist showing absurdly low levels of

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[153] *Id.* 85.

[154] *Id*. at 108:3-14.

[155] *See* Cardinal Health's Memo at 18-19 (Mr. Rafalski "rests on his review of only 'some' of the due diligence files produced in the litigation and the unsupported inference that the absence of old files that Cardinal had no legal obligation to retain meant that the company did not do due diligence.").

[156] 861 F.3d at 218 (quoting DEA Order (quoting 5 Wigmore, Evidence § 1531, at 463)).

suspicious activity reporting. This type of evidence likewise was present and addressed by Judge Polster in his opinion finding Mr. Rafalski's expert opinions admissible and his no due diligence opinion reasonable.[157] Mr. Rafalski's opinion that Defendants, including Cardinal, did not perform adequate due diligence on orders that should have been flagged thus is reasonable based on the evidence of record and on his extensive experience as a DEA Diversion Investigator.

Finally, the Court also should reject Cardinal's suggestion that its low level of suspicious order reporting is appropriate based on Mr. Rannazzisi's testimony that the number of suspicious orders reported under a *properly functioning* SOM system should be low.[158] Mr. Rannazzisi testified that the number of reported suspicious orders should be low because they are not filed until *after* a distributor performs due diligence.[159] The number of reported suspicious orders under a properly functioning system also should be low because, as Mr. Rafalski testified, once a customer's order is flagged, "all future orders that are placed by the same customer[,] [s]pecifically, to the family of the drugs that are held, they should all be stopped."[160] Thus, the

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[157] *See* MDL Rafalski Op., 2019 WL 3934490, at *6 ("Plaintiffs respond that Rafalski's analysis is reliable because it is based on his extensive review of Defendants' SOMS programs, after which he concluded that Defendants conducted little or no due diligence (which is based, at least in part, on their failure to reports suspicious orders and/or document due diligence.") (emphasis added).

[158] *See* Cardinal Memo. at 17.

[159] *See* 6/7 Trial Tr. (Rannazzisi) at 219:17-20 ("It should be a very specific order that outlines why it's suspicious, what triggered the suspicion, what triggered the order, what's the historical ordering pattern."); *see also* 6/8 Trial. Tr. (Rannazzisi) at 95:20-25 ("So, yes, it's the same due diligence problems. You're not, you're not reviewing the customers' orders. You're not comparing those orders. You're just not doing what's appropriate to determine what's suspicious and what's not, and then stop those orders from going downstream.").

[160] 5/26 Trial Tr. (Rafalski) at 78:9-14; *see also* 5/26 Trial Tr. (Moné) at 95:4-97:5 ("Q. The process being laid out here has the customer being terminated from purchasing controlled substances or in totality, correct? A. That is the statement on the slide, yes.").

orders of a customer that is flagged should not pile up if Cardinal properly stops future shipments while an initially-flagged order still is unresolved.

CONCLUSION

For all of the reasons set forth, this Court should deny Cardinal Health's Motion for Judgment Under Rule 52(c).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 25, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ *Anthony J. Majestro*